

II. In the Claims (Marked Version)

Please amend the claims as follows:

1. (Twice Amended) A vaccine for the prevention of *Campylobacter* colonization in animals[, characterized in that said vaccine comprises] comprising an effective amount of antiserum raised against a flagellaless *Campylobacter* strain.
2. (Twice Amended) A vaccine according to claim 1[, characterized in that] wherein the flagellaless *Campylobacter* strain is *Campylobacter jejuni*.
3. (Twice Amended) A vaccine according to Claim 2[, characterized in that] wherein the flagellaless *Campylobacter jejuni* strain is strain 2.
9. (Twice Amended) A vaccine for the prevention of *Campylobacter jejuni* colonization in poultry[, characterized in that said vaccine comprises] comprising an effective amount of antibodies against the antigenic protein comprising a protein of a *Campylobacter* having a molecular weight of 97 kD (+/- 5kD), whereby [characterized in that] it is visible in a Western blot with antibodies against a flagellaless mutant of *Campylobacter jejuni* and that it is not visible after incubation of said blot with antibodies against the wild type *Campylobacter jejuni*.

III. Remarks

A. Response to Final Restriction Requirement

Applicants respectfully request reconsideration of the rejection in light of well-established statutes and case law. The Examiner is correct in stating that the Patent Office can issue a restriction requirement if it finds that two or more inventions claimed in a patent application are "independent and distinct." 35 U.S.C. § 121 (1994); *In re Dembiczak*, 50 USPQ2d 1614, 1620 9Fed. Cir. 1999); and, Man. Pat. Examining Proc. Section 806.05(e) (7th ed. 1998). However, as a biotechnological invention, restriction is improper. Title 35, Section 103(b)(1) states that "[n]otwithstanding subsection [103(a)] and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under [103(a)] shall be considered nonobvious if (a) claims to the process and the composition are contained in either the same application for patent ... (b) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person ... This section shows clear congressional intent to allow the process claims of a corresponding product to be examined at one time. Moreover, it is clear from the statute that examination must take place and that the product cannot be used as a reference to the process. Therefore, in the interests of Patent Office Economy, the restriction requirement should be lifted. Accordingly, Applicants respectfully request that the Examiner lift the restriction requirement as to Claims 12 and 13.

Furthermore, Applicants reiterate that the claims of Group IV should be examined with the Claim of Group I, Claims 1-3 and 9. Claim 12 is dependent from 1 and relates to the same subject matter. Claim 13 depends on amended Claim 9 that includes the limitations of Claim 4. The examination of Claim 12 and 13 with Claims 1-3 and 9

would not place a burden on the Examiner and rather be in the interests of Patent Office economy of effort. Moreover, Claims 12 and 13 are Method claims for making a vaccine "according to" Claims 1 and 9, respectively. Therefore, there is a compelling argument that the restriction requirement should be lifted because of the fact that the majority of the search will necessarily need to be redone at the time of prosecution of the purported other species. Accordingly, Applicants respectfully request that the restriction requirement be lifted.

B. Rejections Under 35 USC §112

Claims 1-3 and 9 stand rejected under 35 USC §112, 2nd ¶ as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner states that Claims 1-3 recite the phrase "characterized in that" and that the meaning of the phrase is not clear. Applicants have amended the claims to conform to United States claim drafting procedures. However, Applicants have not narrowed the scope of the claims, such amendment is typographical and does not alter the scope of the claims.

Claim 3 stands rejected for reciting the term "R2." The Examiner states that the meaning of the term is not clear. Applicants respectfully point out that strain R2 is specifically identified on page 3, lines 23-29 of the specification.

Applicants have incorporated the text of Claim 4 into Claim 9 to overcome the rejection of Claim 9.

Applicants respectfully request reconsideration of the rejections under 35 USC §112, 2nd ¶.

C. Rejections Under 35 USC §102(b)

1. Rejection of Claims 1-2 and 9 by Blaser I

Claim 1-2 and 9 stand rejected under 35 USC §102(b) as being anticipated by an article to Blaser et al. in a journal titled Infection Immunity, Vol. 53(1), July 1986, pp. 47-52 (hereinafter referred to as Blaser I). The Examiner states that the claimed invention of Claims 1 and 2 are directed to a vaccine composition of antiserum directed to a flagellaless of *Campylobacter jejuni* strain. The Examiner further states that Claim 9 is directed to an antigen protein of *Campylobacter*. The Examiner then states, for the examination purposes, the term vaccine is not being read as a limitation, but rather as an intended use.

The Examiner then states that the Blaser I article discloses a flagellaless strain of *Campylobacter* used to produce antiserum in a host. The whole cell flagellaless *Campylobacter* strain comprised the antigens shown in Fig. 1, p. 48, col. 2 and was used to produce the antibody containing antiserum. The Examiner then states that the flagellan antigens are missing but the other antigens are present in the whole cell antigen lane. The Examiner further states that by all comparable data the antiserum comprised the new claimed antibodies inherently. Applicant has amended Claims 1 and 9 to more clearly indicate that Applicant is claiming a vaccine. However, such amendment is not limiting the scope of the claims, but only clarifying that which is apparent from the original claims.

The prosecution of this application is much like the prosecution of the subject application in the case of *Interactive Pictures Corporation V. Infinite Pictures, Inc.*, 01-1029 (Fed. Cir. December 20, 2001). In that case, the Federal Circuit determined that amendments that do nothing more than make express what had been implicit in the claim as originally worded do not act as an estoppel limiting application of the doctrine of equivalents.

In that case, Infinite contended that Interactive narrowed a claim limitation, "image transform processor means," by replacing the words "output signals" with the words "output transform calculation signals," asserting that Infinite is thus barred from asserting any equivalents to that limitation, under *Festo*. In Infinite's view, the amendment changed the nature of the claimed output signals. Infinite further asserts that a more particular recitation of the output signals was necessary to define the invention over the prior art cited prior to the amendment. The Court concluded that the addition of the words "transform calculation" was not a narrowing amendment because that addition did nothing more than make express what had been implicit in the claim as originally worded. That interpretation flows from the original claim as a whole and in light of the specification. Because the amendment merely made explicit what had been implicit in the claim, the amendment was not made for a "substantial reason related to patentability" and thus does not create prosecution history estoppel. *Warner-Jenkinson*, 520 U.S. at 33, 41 USPQ2d at 1873; *see also Turbocare Div. of Deman Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1125-26, 60 USPQ2d 1017, 1028 (Fed. Cir. 2001) (holding that addition of the word "contact" to a claim did not narrow the claim and therefore did not estop application of the doctrine of equivalents for that element because

another claim phrase, "small diameter position," when read in light of the specification, necessarily implied "contact."). Such is the case in the prosecution of the instant application.

Here, the claim as originally filed was for a vaccine. Applicants have done nothing more than add words that the claims are for a vaccine. The addition has done nothing more than make express what had been implicit in the claim as originally worded. Accordingly, the claim amendment does not affect the scope of the claim under the doctrine of equivalents.

The Blaser I article does not teach or suggest vaccines comprising antiserum against a flagellaless *Campylobacter* strain. However, the Blaser I article merely discloses that a *Campylobacter* strain characterized by FM does not display a 63-kDa protein by Western Blotting. (See Abstract). The Blaser I article does not disclose, teach, or suggest a vaccine for the prevention of *Campylobacter* colonization in animals, wherein said vaccine comprises an effective amount of antiserum raised against a flagellaless *Campylobacter* strain. Accordingly, Applicants respectfully request reconsideration of the rejection.

It has long been the law that an "[e]lement of claim is not 'inherent' in [a] disclosure of prior art reference unless extrinsic evidence clearly shows that missing descriptive matter is necessarily present in thing described in reference, and that it would be so recognized by persons of ordinary skill; inherency may not be established by mere probabilities or possibilities, and mere fact that certain thing may result from given set of circumstances is not sufficient." *In re Robertson*, 19 U.S.P.Q.2d 1949, 1951 (Fed.Cir.

1999). Here, the extrinsic evidence does not clearly show a vaccine, as is claimed. Accordingly, Applicants respectfully request that the rejection be removed in light of this response.

2. Rejection of Claims 1-2 by Dolby

Claims 1-2 stand rejected under 35 USC §102(b) as being anticipated by an article to Dolby et al. in a journal titled J. Hyg. Camb., Vol. 96, pp. 143-151, 1986. The Examiner states that the article to Dolby et al. discloses a vaccine composition antiserum that comprises antibodies obtained through immunization with a flagellaless strain of *Campylobacter*. The Examiner then stated that the article to Dolby et al. inherently disclosed Applicants' claimed invention. However, the Dolby article only discloses the use of vaccines of whole cell and outer protein membrane extracts. (See p. 144, 1st ¶ under Vaccines). There is no disclosure of Applicants' claimed invention. *See In re Robertson*, 19 U.S.P.Q.2d at 1951. Dolby does not disclose, teach, or suggest a vaccine for the prevention of *Campylobacter* colonization in animals, wherein said vaccine comprises an effective amount of antiserum raised against a flagellaless *Campylobacter* strain. Accordingly, Applicants respectfully request reconsideration of the rejection in light of this response.

3. Rejection of Claims 1-3 by Cawthraw

Claims 1-3 stand rejected under 35 USC §102(b) as being anticipated by an article by Cawthraw et al. in a journal titled Avian Diseases, April-June, 1994, Vol. 38(2) pp. 341-349. The Examiner states that Cawthraw et al. discloses anti-C.jejuni IgC

antibodies induced to a strain of *Campylobacter jejuni* referred to as R2, a flagellaless strain of *Campylobacter jejuni*. The Examiner states that the Cawthraw et al. article inherently disclosed the claimed invention. However, there is no disclosure, teaching, or suggestion a vaccine for the prevention of *Campylobacter* colonization in animals, wherein said vaccine comprises an effective amount of antiserum raised against a flagellaless *Campylobacter* strain. Accordingly, Applicants respectfully request reconsideration of the rejection. The Cawthraw article is a study of the immunodominance of flagellan, not a study or a disclosure of a vaccine for *Campylobacter*. The Cawthraw article does not clearly show that missing descriptive matter (i.e. Applicants' claimed vaccine) is necessarily present in the description in reference, and it would not be so recognized by persons of ordinary skill. As is the law, inherency may not be established by mere probabilities or possibilities, and mere fact that certain thing may result from given set of circumstances is not sufficient." *In re Robertson*, 19 U.S.P.Q.2d at 1951. Accordingly, Applicants respectfully request reconsideration of the rejection in light of this response.

4. Rejection of Claim 9 by Blaser II

Claim 9 stands rejected under 35 USC §102(b) as being anticipated by an article to Blaser et al., in a journal titled Journal of Infectious Diseases, Vol. 167(2), pp. 372-377, Feb. 1993 (hereinafter referred to as Blaser II). The Examiner states that Blaser II discloses a vaccine composition of antibodies induced to a *Campylobacter* antigen. The Examiner further states the antibodies were formulated into a vaccine composition and administered to an animal to provide protection against challenge with a pathogenic strain

of a *Campylobacter*. The Examiner then concludes that the antibodies administered provided partial protection against lethal challenge and therefore function as a vaccine and inherently anticipate Applicants' invention. Applicants respectfully request reconsideration in light of this response.

Applicants point out that the *Campylobacter jejuni* of the present invention has no S-layer and consequently no S-layer protein. Accordingly, the 97 kDa S-layer protein present in the *Campylobacter foetus* that the Examiner refers to as a comparison to Applicants' invention is not present in Applicants' invention. For further verification, the Examiner can look at the protein data bank at 'www.NCBI.nlm.nih.gov' which discloses the full genome of *Campylobacter jejuni*. The database returns no proteins for the S-layer for *C. jejuni*. Accordingly, Applicant respectfully requests reconsideration of the rejection in light of this response.

5. Rejection of Claim 9 by Kervella

Claims 9 stands rejected under 35 USC §102(b) as being anticipated by an article to Kervella et al, in a journal titled Infection Immunity, August 1993, Vol. 61(8), pp. 3440-3448. The Examiner states that the article discloses a composition of antibodies to an outer membrane antigen of *Campylobacter jejuni* referred to as P92, on p. 3447, col. 2. The Examiner then states that inherently the antibodies in the article by Kervella anticipate Applicants' invention. However, the Examiner has failed to set forth any extrinsic evidence that would show that the Kervella article. Moreover, as stated above, the *Campylobacter jejuni* strain of the present invention has no S-layer proteins.

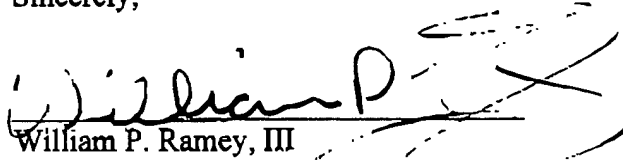
Accordingly, the Kervella article does not disclose Applicants' invention. Therefore, Applicants respectfully requests that the rejection be lifted.

IV. Conclusion

Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Please call the below undersigned attorney for any assistance in securing allowance of this application. Please charge deposit account number 02-2334 for any required fees.

Date: 1/21/02

Sincerely,


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